# HEPATITIS C
## (Previously known as Non-A, Non-B Hepatitis and HCV Infection)

## ✓DISEASE AND EPIDEMIOLOGY

### Clinical Description:

#### Symptoms - Acute

Initial hepatitis C infection is often asymptomatic (~80% of cases) or mild; therefore, it is uncommon for people to be diagnosed with HCV infection in the acute stage. If clinical illness does occur, symptoms begin about 7 weeks after infection and can include: jaundice, fatigue, dark urine, abdominal pain, loss of appetite, and nausea. About 15–25% of HCV-infected individuals recover spontaneously (reasons for this are still unknown); the rest develop chronic infection. Hepatitis C is a disease with varying rates of progression. In general, however, its course is slowly progressive.

#### Symptoms – Chronic

Most people are asymptomatic during the first decade or two of chronic HCV infection. Some patients will experience a range of symptoms including fatigue, headache, joint aches, muscle aches, nausea, jaundice, loss of appetite, and/or abdominal pain.

For many with chronic hepatitis C, signs and symptoms appear only when liver disease is advanced. Almost 70% of those with chronic HCV infection develop chronic liver disease, a situation in which the virus damages the liver. The damage may progress to severe disease, including cirrhosis, liver cancer, and liver failure.

Severe disease or cirrhosis symptoms include fatigue, muscle weakness, poor appetite, nausea, weight loss, itching, dark urine, fluid retention, and abdominal swelling.

### Causative Agent:

**HCV** is a spherical, enveloped, single-stranded RNA virus belonging to the Flaviviridae family and Flavivirus genus. HCV is closely related to hepatitis G, dengue, and yellow fever viruses. HCV can produce at least 10 trillion new viral particles each day. Six major HCV genotypes and numerous subtypes have been identified.

**Genotypes**

- The major HCV genotype worldwide is genotype 1, which accounts for 40-80% of all isolates.
- Genotypes 1a and 1b are prevalent in the United States.
- Genotypes 2 and 3 are also found globally and account for a significant minority of infections.
- HCV genotype 1, particularly 1b, does not respond to therapy as well as genotypes 2 and 3.

- Genotype 1 also may be associated with more severe liver disease.

**Hepatitis G virus** (also known as GB Virus Type C) is a closely related virus. Currently, it is not known if this virus causes illness. Approximately 2-5% of people in the U.S. carry antibodies against this virus.

## Differential Diagnosis:

The major conditions that can be confused clinically with acute hepatitis C include:

- acute hepatitis A and B
- drug induced hepatitis
- alcoholic hepatitis
- autoimmune disorders

The major conditions that can be confused clinically with chronic hepatitis C include:

- autoimmune hepatitis
- chronic hepatitis B and D
- alcoholic hepatitis
- nonalcoholic steatohepatitis (fatty liver)
- sclerosing cholangitis
- Wilson's disease
- alpha-1-antitrypsin-deficiency-related liver disease
- drug-induced liver disease

## Laboratory identification (see Appendix C and D ):

The following tests are available to diagnose Hepatitis C:

- Anti-HCV screening test (may have signal to cut-off ratio predictive of a true positive)
- HCV RIBA
- NAT or HCV RNA
- Six major HCV genotypes and numerous subtypes have been identified (1a, 1b, 1c, 2a, 2b, 3a, 4, 5a, 6)
- Elevated liver enzymes (90% of acute hepatitis C cases had ALT levels >400 IU/L, only 1% of chronically infected persons had ALT levels that high).

Most patients with chronic hepatitis C have levels of HCV RNA (viral load) between 100,000 ($1X10^5$) and 10,000,000 ($1X10^7$) copies per mL. Expressed as IU, these averages are 50,000 to 5 million IU.

Viral levels as measured by HCV RNA do not correlate with the severity of the hepatitis or with a poor prognosis (as in HIV infection); but viral load inversely correlates with the likelihood of a response to antiviral therapy (e.g. cases with low initial viral load levels have a better therapeutic outcome than cases with high initial viral load levels.)

**Utah Public Health Laboratory (UPHL)** has the ability to perform anti-HCV testing on patients.

## Treatment:

The FDA has approved the following antiviral therapies for treatment of chronic hepatitis C in persons 18 years and older:

1) Interferons
   a. Alpha Interferon
   b. Pegylated Interferon
2) Ribavirin
3) Protease inhibitors
   a. Incivek (telaprevir)- approved by the FDA in May of 2011
   b. Victrelis (boceprevir)- approved by the FDA in May of 2011

   *Note:* The following Veteran's Affairs website provides additional information about treatment with protease inhibitors, and may be a valuable supplemental resource in providing treatment education. http://www.hepatitis.va.gov/provider/index.asp

Treatment duration

- Treatment with an interferon and ribavirin can last up to 52 weeks, depending on genotype.
- Triple combination therapy with interferon, ribavirin and a protease inhibitor can reduce treatment time from up to 52 weeks to 24 weeks, with 90% of eligible patients being cured.

Treatment response

- Among persons with HCV genotype 1, the response rate to either of the interferons given alone is 20% or less.
- Response rate to the double combination of alpha interferon and ribavirin is 30%-40%.
- Response rate to the double combination of pegylated interferon and ribavirin 40%-50%.
- Triple combination therapy of alpha or pegylated interferon, ribavirin and protease inhibitors can achieve a cure of hepatitis C in 90% of patients who are eligible for treatment.
- Genotypes 2 and 3 can be treated with combination therapy of ribavirin and the interferons with nearly an 80% effectiveness of treatment.
- Studies have not been conducted on genotypes 2 and 3 with the protease inhibitors and their effectiveness is unknown.

Efficacy of protease inhibitors

- The protease inhibitors (boceprevir and telaprevir) work by binding to the hepatitis C virus and preventing it from multiplying. These medications are effective only against genotype 1.
- Incivek(telaprevir) is indicated for use in patients who have not received previous interferon-based drug therapy or who have not responded adequately to previous therapies. Incivek is approved for use with interferon therapy made up of pegylated or alpha interferon and ribavirin.
- The safety and effectiveness of Incivek was evaluated in three clinical trials with about 2,250 adult patients who were previously untreated, or who had received prior therapy. In all studies patients also received the drug with interferon and ribavirin. In previously untreated patients, 79 percent of those receiving Incivek

experienced a sustained virologic response (i.e., the infection was no longer detected in the blood 24 weeks after stopping treatment) compared to standard treatment alone.

- The sustained virologic response for patients treated with Incivek as shown in the studies, was between 20 and 45 percent higher than current standard of care; the combination therapy of interferon and ribavirin (approx 50%).
- Victrelis(boceprevir) is indicated for use in patients who do have some liver function, and either have not received previous treatment or who have not responded adequately to previous therapies. Victrelis is approved for use in combination with pegalyted or alpha interferon and ribavirin.
- The safety and effectiveness of Victrelis was evaluated in two clinical trials with 1,500 adult patients. In both trials, two-thirds of patients receiving Victrelis in combination with pegylated interferon and ribavirin experienced a significantly increased sustained virologic response (i.e., the hepatitis C virus was no longer detected in the blood 24 weeks after stopping treatment), compared to pegylated interferon and ribavirin alone, the current standard of care.

Treatment success

- There are several factors that can affect treatment success, which include viral genotype, viral load, gender, ethnicity, length of infection, blood iron levels, obesity, alcohol usage, HIV infection, and adherence to therapy. Further information on these factors can be obtained from the VA's website: http://www.hepatitis.va.gov/patient/treat/decisions-treatment-outcome-factors.asp
- When a person sustains a virologic response after completing treatment, this suggests that HCV infection has been cured. Sustained virologic response can result in decreased cirrhosis and complications of liver disease, decreased rates of liver cancer (hepatocelluar carcinoma), and decreased mortality.

Side effects

- Common side effects for any therapy regimen can include: flu like symptoms, anemia, fatigue, rash, hair thinning, headaches and gastro intestinal upset.
- Since the duration of treatment is substantially reduced with the addition of the protease inhibitors, triple combination therapy reduces the length of time side effects may occur.

The University of Utah conducts clinical trials on study hepatitis medications and often is looking for individuals to participate. For further information, contact UDOH epidemiology 801-538-6191 who can give you information for who to contact about arranging clinic visits or inclusion in clinical trials that use hepatitis B or C medications.

## Case fatality:

Each year, 8,000 to 10,000 people die from the complications of liver disease caused by hepatitis C.

## Reservoir:

Humans are the only known reservoir of this virus.

## Transmission:

HCV is a bloodborne pathogen that is predominantly spread via exposure to contaminated blood or blood products. Currently, the most prevalent mode of transmission is sharing needles or syringes to inject drugs, tattoos and body piercings. Blood transfusions pose an extremely limited risk now, but for patients who received a blood transfusion prior to June 1992, the risk of infection was approximately 1.5% per transfusion recipient. Sexual transmission of HCV is very low, but can occur. The risk of sexual transmission increases with multiple partners, coinfection with HIV, MSM, anal sex and any other sexual activity where blood may be exchanged. Other potential risks for transmission include:

- Long-term hemodialysis
- Sharing straws for intranasal cocaine use
- Vertical (mother to infant) transmission (the risk of perinatal transmission is estimated to be about 5%, although if the mother is co-infected with HIV, the risk may be approximately 15–25%)
- Occupational blood exposure (the risk of occupational exposure for health care workers has been estimated to be 1.8% per incident of hollow-bore needlestick exposure to HCV-infected blood)
- Various medical procedures (including dental)
- Tattooing or body piercing with non-sterile equipment

HCV is not spread through casual contact, kissing, sneezing, hugging, and sharing glasses or utensils, or breast milk.

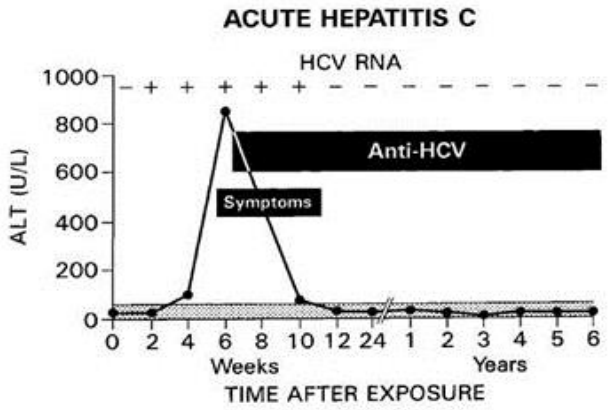
## Susceptibility:

HCV infection occurs among persons of all ages; with the highest incidence of acute HCV infection (new cases) occurring among persons aged 20–30 years. Cases may be infected by more than one genotype, but this is rare. Patients can be treated for one genotype, and be re-infected via another genotype.

## Incubation period:

The incubation period for HCV ranges from 2 weeks to 6 months, with an average incubation period of 6–7 weeks.

A)

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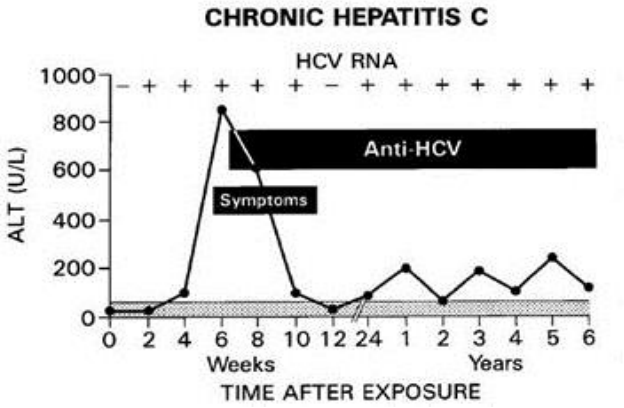



## Period of communicability:

Infectiousness with HCV is variable; anyone with a positive test for HCV antibody should be considered infectious. The virus can usually be detected by the presence of viral RNA in an infected person's blood within 1–3 weeks after the initial exposure. The degree of correlation between quantity of circulating virus and infectiousness is not clearly established.

## Epidemiology:

HCV has a worldwide distribution. In the U.S., an estimated 4 million people are infected with HCV; it is thought that there are currently about 19,000 new cases of acute HCV infection each year. The overall incidence in 2006 as estimated by the CDC was 0.3 cases per 100,000 persons. Prevalence is highest among groups with specific risk factors, especially injection drug users, patients with hemophilia or on long-term hemodialysis, prison inmates, and people who received blood or organ products prior to June 1992.

Most of these newly reported cases are not people with new (acute) disease but those with chronic infection who have been newly diagnosed. There remains a large population

of undiagnosed people who were infected in the past. It is estimated that only 1 out 4 individuals with HCV know they are infected.

A segment of the population of particular interest is the baby boomers, or those U.S. citizens born between 1945 and 1965. Statistics show that baby boomers account for more than 75 percent of all American adults living with the hepatitis C virus and are considered five times more likely to be infected than other adults. CDC estimates that more than 2 million (nearly 1 in 30) baby boomers have been infected with hepatitis C with most unaware of their infection. CDC recommends that all baby boomers should get a onetime test for hepatitis C. This approach will address the largely preventable consequences of this disease, especially in light of newly available therapies that can cure up to 75 percent of infections. For more information, see the CDC press release from May 18, 2012:
http://www.cdc.gov/nchhstp/newsroom/HepTestingRecsPressRelease2012.html

# ✓PUBLIC HEALTH CONTROL MEASURES

## Public health responsibility:

- To provide information to HCV-infected persons on how to prevent exposing others.
- To provide information to HCV-infected patients on the importance of medical evaluation and why continued care is needed, how to reduce disease progression and to provide referrals to medical or supportive facilities for these services.
- To determine the prevalence of HCV in specific populations and geographic locations to help guide HCV prevention and education activities.
- To identify clusters of HCV cases or outbreaks, in particular, those that appear to involve health care-associated transmission.
- Investigate all suspect cases of disease in cases under 30 years of age, pregnant women over 30 years old, individuals coinfected with HIV/AIDS or hepatitis B, and suspect acute cases of HCV (defined as ALT >400 and or jaundice) by completing and submitting appropriate disease investigation forms.
- Provide education to the general public, clinicians, and first responders regarding disease transmission and prevention.
- Identify sources of exposure and prevent further transmission.
- Provide routine surveillance to determine at risk groups for public health intervention.

## Prevention:

The goals of hepatitis C prevention and control efforts are:

1) To reduce the incidence of new infections by reducing HCV transmission
2) To reduce the risk of chronic liver disease in HCV-infected individuals through appropriate medical management and counseling.
3) Educate infected persons on how to care for themselves and how to avoid spreading infection to others.

## Chemoprophylaxis:
There is currently no post-exposure prophylaxis for hepatitis C, although treatment is available.

## Vaccine:
There is currently no vaccine for hepatitis C.

## Isolation and quarantine requirements:
**Isolation:** None
**Hospital:** Body substance precautions.
**Quarantine:** None

No restrictions except for exclusion from organ and blood donation and counseling to modify activities in order to prevent transmission.

There are no specific regulations regarding HCV infection in daycare, school, or community residential programs. HCV is not spread via casual contact or through food or water. As long as standard precautions are maintained, HCV will not be spread to others in these settings. No one who is HCV-infected should be excluded from attending or working in any of these settings on the basis of his/her HCV infection.

# ✓CASE INVESTIGATION
## Reporting:
- All cases of HCV infection are reportable to public health. All acute cases will be investigated (cases with elevated ALT (> 400) or other symptoms of acute hepatitis: jaundice, nausea, RUQ pain, etc.)
- Chronic and non-acute cases in any of the following groups will be investigated:
    - Individuals 30 years and younger
    - Individuals with a coinfection of HIV/AIDS or hepatitis B
    - Pregnant women over 30

**CSTE Reporting Swimlanes**

| Criterion | Reporting |
|---|---|
| ***Clinical and Administrative Data*** | |
| Healthcare record contains a diagnosis of hepatitis C | S |
| Death certificate lists hepatitis C as a cause of death or a significant condition contributing to death | S |
| ***Laboratory Evidence*** | |
| Antibodies to hepatitis C virus (anti-HCV) screening-test-positive | S |
| Antibodies to hepatitis C virus (anti-HCV) screening-test-positive with a signal to cut-off ratio predictive of a true positive as determined for the particular assay as defined by CDC | S |

| | |
|---|---|
| Hepatitis C Virus Recombinant Immunoblot Assay (HCV RIBA) positive | S |
| Nucleic Acid Test (NAT) for HCV RNA positive | S |

Notes:
S = This criterion alone is sufficient to report a case.

# Case definition:

## Hepatitis C (2011):

### Clinical Description

- **Acute Definition**: An acute illness with a discrete onset of any sign or symptom consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, abdominal discomfort, nausea, vomiting), and either a) jaundice, **OR** b) serum alanine aminotransferase (ALT) levels >400 IU/L.
    - **NOTE**: 90% of acute hepatitis C cases had ALT levels >400 IU/L, only 1% of chronically infected persons had ALT levels that high.
- **Chronic Definition:** A person with or without symptoms.

### Laboratory Criteria

- **Acute Diagnosis:**

Meets one or more of the following three criteria:

1) Antibodies to hepatitis C virus (anti-HCV) screening-test-positive with a signal to cut-off ratio predictive of a true positive as determined for the particular assay as defined by CDC. (URL for the signal to cut-off ratios: http://www.cdc.gov/ncidod/diseases/hepatitis/c/sc_ratios.htm), **OR**
2) Hepatitis C Virus Recombinant Immunoblot Assay (HCV RIBA) positive, **OR**
3) Nucleic Acid Test (NAT) for HCV RNA positive (including qualitative, quantitative or genotype testing)

    **AND**, meets the following two criteria:

    1) IgM antibody to hepatitis A virus (IgM anti-HAV) negative, **AND**
    2) IgM antibody to hepatitis B core antigen (IgM anti-HBc) negative

    Note: Diagnosis of acute disease can be problematic because anti-HCV is not always present when the patient develops symptoms and sees the physician.

    In 30% to 40% of patients, anti-HCV is not detected until 2 to 8 weeks after onset of symptoms. In this situation, testing for HCV RNA is helpful, as this marker is present even before the onset of symptoms and lasts through the acute illness.

    Another approach to diagnosis of acute hepatitis C is to repeat the anti-HCV testing a month after onset of illness.

**CSTE Acute HCV Swimlanes**

| | **Case Definition** | | |
|---|---|---|---|
| **Criterion** | **Confirmed** | | |
| ***Clinical evidence*** | | | |
| Acute Onset | N | N | |
| Jaundice | N | | |
| Fever | O | O | |
| Headache | O | O | |
| Malaise | O | O | |
| Anorexia | O | O | |
| Nausea | O | O | |
| Vomiting | O | O | |
| Diarrhea | O | O | |
| Abdominal Pain | O | O | |
| ***Laboratory evidence*** | | | |
| Elevated serum aminotransferase (ALT) levels >400IU/L | | N | O |
| Antibodies to hepatitis C virus (anti-HCV) positive with a signal to cut-off ratio predictive of a true positive as determined for the particular assay and posted by CDC | O | O | O |
| Hepatitis C Virus Recombinant Immunoblot Assay (HCV RIBA) positive | O | O | O |
| Nucleai Acid Test (NAT) for HCV RNA (including qualitative, quantitative, or genotype testing) positive | O | O | O |
| IgM antibody to hepatitis A virus* (IgM ant-HAV) | A | A | A |
| IgM antibody to hepatitis B core antigen* (IgM anti-HBc) | A | A | A |
| Negative test with-in 6 months of a positive test | | | N |

*****=Test is not required but if done must be reported

**A**= If this test was completed the criterion must be absent

**N**= This criterion in conjunction with all other "N" and any "O" criteria in the same column is required to classify a case.

**O**= At least one of these "O" criteria in each category in the same column (clinical evidence and laboratory evidence) in conjunction with all other "N" criteria in the same column is required to classify a case.

- **Past or Present Diagnosis:**

*Hepatitis C Virus Infection, Past or Present (2011 Case Definition):*

Anti-HCV positive (repeat reactive) by EIA, verified by an additional more specific assay (e.g. RIBA for anti-HCV or nucleic acid testing for HCV RNA),

**OR**

Is hepatitis C virus recombinant immunoblot assay (HCV RIBA) positive,

**OR**

Nucleic acid test (NAT) for HCV RNA positive (including qualitative, quantitative and genotype testing)

**OR**

Anti-HCV screening-test-positive with a signal to cut-off ratio predictive of a true positive as determined for the particular assay as defined by CDC. (URL for the signal to cut-off ratios: http://www.cdc.gov/ncidod/diseases/hepatitis/c/sc_ratios.htm)

Note: Chronic hepatitis C is diagnosed when anti-HCV is present and serum aminotransferase levels remain elevated for more than 6 months.

Testing for HCV RNA (by PCR) confirms the diagnosis and documents that viremia is present; almost all patients with chronic infection will have the viral genome detectable in serum by PCR.

Most patients with chronic hepatitis C have levels of HCV RNA (viral load) between 100,000 ($10^5$) and 10,000,000 ($10^7$) copies per mL. Expressed as IU, these averages are 50,000 to 5 million IU.

**CSTE Past or Present Swimlanes**

| | **Case Definition** | | |
|---|---|---|---|
| **Criterion** | **Confirmed** | | **Probable** |
| ***Laboratory evidence*** | | | |
| Elevated serum aminotransferase (ALT) levels | | | N |
| Anti-HCV positive (repeatedly reactive) by EIA | | | N |
| Antibodies to hepatitis C virus (anti-HCV) positive with a signal to cut-off ratio predictive of a true positive as determined for the particular assay and posted by CDC | O | | |
| Hepatitis C Virus Recombinant Immunoblot Assay (HCV RIBA) positive | O | | |
| Nucleic Acid Test (NAT) for HCV RNA (including qualitative, quantitative, or genotype testing) positive | O | N | |
| ***Epidemiology evidence*** | | | |
| Does not meet the case definition for acute hepatitis C | N | N | N |
| Less than 18 months of age | | N | |

**Notes:**
**N**= This criterion in conjunction with all other "N" and any "O" criteria in the same column is required to classify a case.
**O**= At least one of these "O" criteria in each category in the same column (laboratory evidence and epidemiology evidence) in conjunction with all other "N" criteria in the same column is required to classify a case.

## Case Classification

- ***Acute Confirmed:*** a case that meets the clinical case definition is laboratory confirmed, and is not known to have chronic hepatitis C.

- ***Chronic Probable:*** a case does not meet the case definition for acute hepatitis C, is anti-HCV positive (repeat reactive) by EIA and has alanine aminotranferase (ALT or SGPT) values above the upper limit of normal, but the anti-HCV EIA result has not been verified by an additional more specific assay or the signal to cutoff ratio is unknown.

- ***Chronic Confirmed*****:** a case that is laboratory confirmed and that does not meet the case definition for acute hepatitis C.

### Nosocomial:

Nosocomial outbreaks are uncommon with hepatitis C, but could occur with lack of infection control. Contact UDOH for assistance in any (suspect or confirmed) nosocomial hepatitis C outbreaks or occurrences.

## Case Investigation Process:

See appendix A at the end of this document for a checklist which is a guidance document that suggests a sequence for investigation, recommended elements of investigation, and information that should be reviewed with each case. It is not required and does not need to be submitted with the case report form. The LHD may wish to keep it on file to document the investigation.

The following individuals should be entered in UT-NEDSS as a morbidity event and investigated by the local health departments:

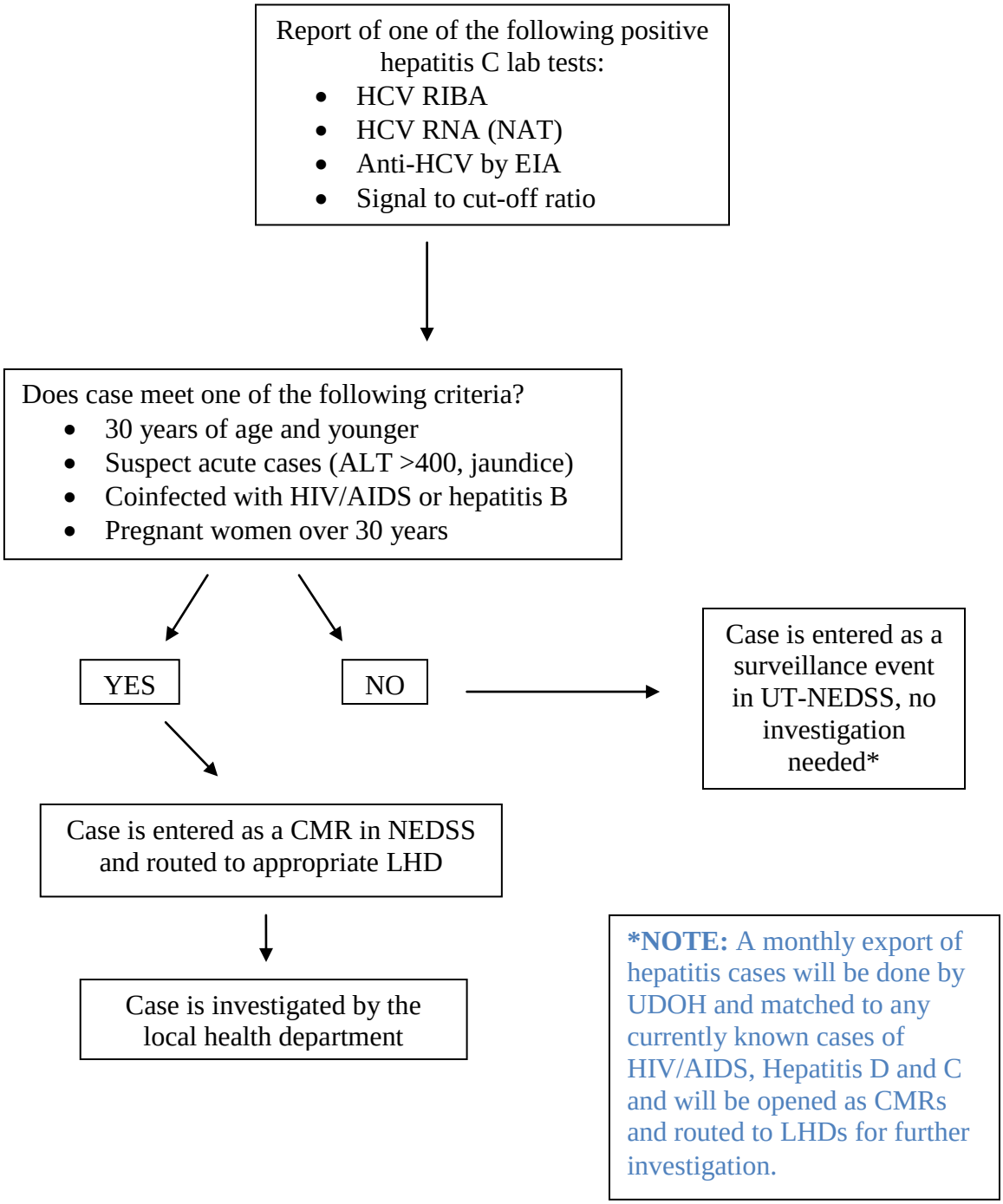
- All cases 30 years of age and younger
- All suspect acute cases (report of ALT >400)
- All cases who are known to be co-infected with HIV/AIDS, or hepatitis B
- Pregnant women over the age of 30

All reports for individuals who do not meet the above criteria will be entered into UT-NEDSS as surveillance events and do not need to be investigated. The surveillance events will be assigned a case status and routed through NEDSS and closed. These records will be counted in routine reports.

## Surveillance:

On a routine basis, records of acute and past or present hepatitis C infections from UT-NEDSS will be collated and analyzed in geocoding software to determine areas of highest prevalence so public health interventions can be initiated. For complete surveillance guidelines, see the hepatitis C surveillance guidelines document here: http://health.utah.gov/epi/disease_plans_forms_factsheets.html.

All cases of hepatitis C will follow the following algorithm:



## Outbreaks:

An outbreak will be defined as: 3 or more acute cases with similar risk exposures.

## Identification of case contacts:

Identification of case contacts will made during an outbreak situation only. Otherwise, encourage case to speak to people who may have been exposed to his/her blood since the time he/she is estimated to have been exposed, infected, or seroconverted.

## Special Situations - Case contact management:

- **Percutaneous and Mucosal Exposure to HCV Infection**

Perform testing for anti-HCV and ALT 4-6 months after exposure. Perform HCV-RNA testing at 4-6 weeks if earlier diagnosis of HCV is desired. Confirm repeatedly reactive anti-HCV test with supplemental test if necessary (if signal-to-cut-off test not used).

- **Pregnant women**

Routine testing for HCV infection is not recommended for all pregnant women. Pregnant women with a known risk factor for HCV infection should be offered counseling and testing. Patients should be advised that approximately six of every 100 infants born to HCV-infected woman become infected; this infection occurs predominantly during or near delivery, and no treatment or delivery method—such as caesarian section—has been demonstrated to decrease this risk. The risk is increased, however, by the presence of maternal HCV viremia at delivery and also is greater (2–3 times) if the woman is coinfected with HIV.

- **Infants born to anti-HCV mother**

The American Academy of Pediatrics recommends screening infants born to mothers who are HCV infected. The diagnosis of HCV is based on detection of IgG antibody and/or HCV RNA by PCR. In infants the persistence of passively acquired maternal antibodies can last up to 12 months. Therefore, testing for anti-HCV antibodies should be performed after 12 months of life. However, a supplemental confirmatory test should be performed, such as the recombinant immunoblot assay (RIBA) or nucleic acid test (NAT), if a signal to cut-off ratio antibody test was not performed.

PCR can be used initially for early diagnosis. In several studies, high maternal viremia and positive HCV-RNA are predictors for vertical transmission rate, as well as maternal co-infection with HIV. Co-infection with HIV both accelerates the clinical progression of hepatitis C and increases the risk of perinatal HCV transmission from 5% (range, 3-8%) to 17% (range, 7-36%).

Due to higher costs of PCR essays, it may be preferable to test high-risk infants after 1 month of age, at the time of well-baby checkup. A negative HCV-RNA result strongly suggests that the infant is not infected, although a confirmatory retest after 18 month is advised. A positive HCV-RNA test increases the post-test probability that the infant is infected with HCV. The time until the repeat test is unclear, but at least 3-4 months apart.

HCV has not been shown to be transmitted through breast milk, although HCV-positive mothers should consider abstaining from breastfeeding if their nipples are cracked or bleeding. Infants born to HCV-positive mothers should be tested for HCV infection and, if positive, evaluated for the presence of chronic liver disease (CLD).

## ✓REFERENCES

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# APPENDIX A: Hepatitis C LHD Action Steps

*This is for LHD use as a quick-reference guide to hepatitis C case investigation activities. It is a suggested sequence of investigation and information that should be reviewed with each case.* Upon receiving a report of acute HCV infection from UDOH, a laboratory or a health care provider, please follow the process detailed below:

**1. Contact the case's health care provider**

- □ Attempt to contact the health care provider by phone to confirm the diagnosis.
- □ If no response after three attempts, send a form via fax or a letter.
- □ If a letter needs to be sent, it should include the following:
    - Case's name;
    - Description of your responsibility to notify and educate the case;
    - Indication that you have been trying to reach the provider;
    - Timeline of when you intend to contact the case;
    - It is strongly preferred that the provider inform the case of her/his diagnosis;
    - Information on how the provider can contact you.
- □ You may include a copy of the UDOH *Hepatitis C Case Report Form* with the fax or letter, and indicate the sections that the provider should fill out or submit a confidential morbidity form.
- □ Include a self-addressed, stamped envelope in which the case report may be returned.

**2. Talking to the case's health care provider**

- □ Explain that the information obtained is strictly confidential, and discuss purpose of surveillance, as necessary.
- □ Confirm the report and diagnosis.
- □ Obtain copies of any additional related laboratory reports, including:
    - EIA – HCV antibody (e.g., ELISA);
    - Immunoblot assay (e.g., RIBA™, SIA);
    - HCV RNA (e.g., RT-PCR, b-DNA); or
    - Liver function tests
- □ Obtain as much information for the case report as possible—if the provider refuses to provide risk-related information, attempt to get demographic information and laboratory results (listed above).
- □ Inform the provider that he/she should discuss this report with the case. The provider should inform the case that someone from the LHD will contact him/her.
- □ Find out when it will be possible for you to contact the case directly. Ask how much time the provider needs to contact the case. A week is recommended.

**3. Contacting the case**

- □ Use the method(s) you normally use to contact the case. This might include attempting to contact the case via phone first. If there is no phone number available or if there is no answer after three tries over at least one week, a home visit can be conducted, if feasible. Alternatively, a letter can be sent to the case's

address. This letter should be non-specific and should discuss a public health concern that you need to discuss with the case.

- □ If a letter needs to be sent:
  - Send the letter via certified mail.
  - Ask in the letter what the best way for you to contact the case would be; then follow the rest of the investigation as indicated below.
- □ If no contact is made with the case four weeks after having sent the certified letter, enter all information obtained on the case at that point into UT-NEDSS. Please note on the form the reason(s) why it could not be filled out completely (i.e., "could not locate patient," "lost to follow-up," etc.

**4. Once you have contacted the case**

- □ Explain confidentiality and the purpose of obtaining the requested information.
- □ Inform the case that the information that will be discussed is highly personal, that it is asked of every person with hepatitis C, and that it is important for our understanding hepatitis C.
- □ Ask the case if they have any questions about HCV or surveillance; refer the case to UDOH if they have questions and need additional information.
- □ Determine if a provider is currently treating the case, and what that provider's specialty is.
- □ If the case is not currently receiving medical care:
  - Suggest that he/she contact a primary care provider for treatment evaluation.
  - As necessary, provide a referral to a primary care provider.
  - Discuss the benefits of ongoing medical care.
  - Discuss the benefits of being assessed by a specialist.
- □ Review HCV transmission with the case—risks, behaviors, and prevention; use the case report form to guide your discussion.
- □ If the case is actively injecting drugs, refer to treatment programs and needle exchange programs.
- □ Discuss the potential for sexual transmission with the case. If the case is concerned about sexual transmission:
  - Recommend using a condom to reduce the likelihood of exposing sexual partners to HCV.
  - Review proper condom use, as necessary.
- □ Discuss the risks of alcohol consumption with the case.
  - Assess whether the case currently drinks alcohol.
  - If they currently drink alcohol recommend elimination of any alcohol consumption—refer to alcohol treatment/support, as necessary.
- □ Recommend that the case discuss any medication use (including alternative/herbal medications) with a provider to ensure that they are not going to damage his/her liver.
- □ Determine if the case is at risk for either hepatitis A or B. If so, provide referral so that the case may receive vaccines to prevent these infections.
- □ Fill out the case report form based on your discussion with the case—if there are additional sections for which you require information, query the case directly. Fill

in information that was not obtained from the health care provider to the extent possible.

- □ Provide the case with a fact sheet on HCV and any other relevant materials.
- □ Provide a phone number for the case to call to get additional information later, if needed.

**5. The following guidelines are to assist in completing the hepatitis C case report form in UT-NEDSS.**

- Accurately record all demographic information indicated on the form.
- Record all available clinical information, including diagnosis and onset dates, symptoms, laboratory tests and dates, and clinician contact information.
- Record the patient's risk history. Some questions on the case report form are quite personal and should be asked in a sensitive manner.
    - Ask about alcohol use to identify if health education is needed and to assess for other possible causes of liver damage.
    - For all of the risk-related questions on the case report form, it is essential that no assumptions be made about the case's risk. Get the information concretely from the individual or from the health care provider(s), or indicate that the risk is unknown for that case.
- Reassure the patient that all information is kept strictly confidential.
- LHD responsibility in working with the individual or health care provider extends only to obtaining the information, where possible, and providing related health education.
    - Educate the patient about preventing transmission (see appendix B) and ways to protect her/his liver. Encourage him/her to speak to people who may have been exposed to his/her blood since the time he/she is estimated to have been exposed, infected, or seroconverted.

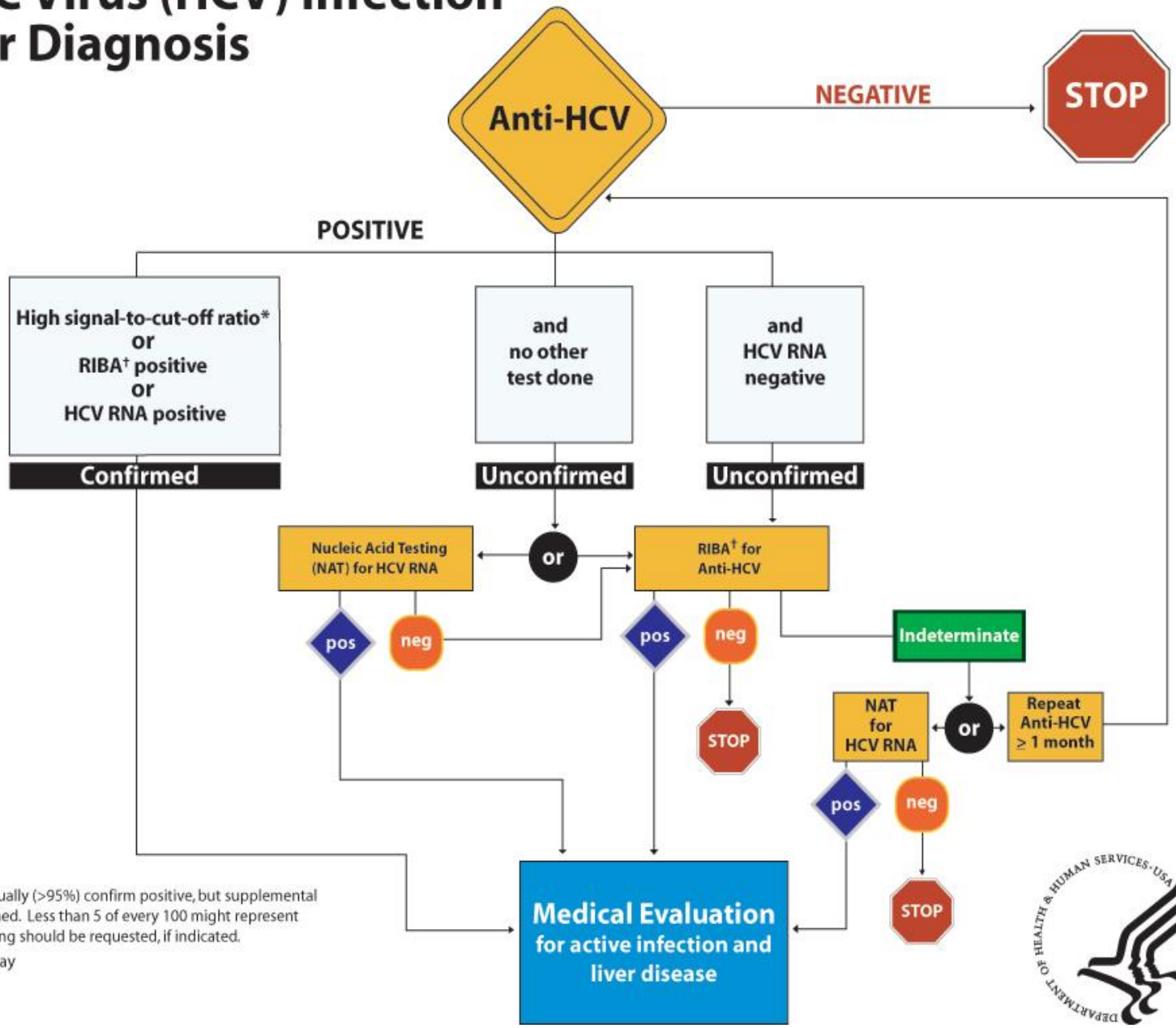
## APPENDIX B: Hepatitis C Patient Education

Prevention and education includes providing information on how the disease is transmitted, how to prevent spread of infection, how patients can protect themselves from other potential sources of liver damage, and treatment options available. Offer the information and support below to newly identified cases:

- Provide basic instruction on transmission of HCV and emphasize the need for ongoing medical evaluation. Treatment is available and the case should be referred to his/her health care provider for a discussion of treatment options.
- Discuss sexual transmission of HCV. Indicate that HCV may be transmitted during sex. Monogamous sexual partners are at lower risk of transmission than those with multiple partners. All contact with blood during sex should be avoided. Emphasize latex barrier protection as a way to prevent the spread of HCV as well as a way to prevent exposure to and transmission of other pathogens.
- Discuss household transmission of HCV. Household transmission is rare, but to ensure that it does not happen, the case should not share razors, toothbrushes, nail clippers, or any other item that could be contaminated with blood.
- If the patient is a current injection drug user, provide referrals to drug treatment and needle exchange programs, if the case needs or wants support to stop using. This will help prevent the spread to other individuals.
- Educate the case on the need to abstain from alcohol to help protect the liver. If a case needs or wants support to stop drinking, provide referrals to appropriate treatment or support services.
- Discuss medications that should be avoided (e.g., acetaminophen) as high doses can damage the liver. All cases should discuss medications (including over-the-counter medications), and dietary supplements and herbs with a health care provider to be certain that they will not damage their livers.
- Determine if case is at risk for either hepatitis A or B. If so, provide information on hepatitis A and hepatitis B immunization. (Refer to the *Hepatitis A* and *Hepatitis B* disease plans for more information.)
- Inform the case that he/she should not be restricted from working, preparing food, or taking part in his/her daily activities unless he/she has specific symptoms that make it difficult to do so. There are no recommendations suggesting that HCV-infected persons should change their exercise routines or have any dietary restrictions.
- Discuss treatment options available to the case. With the new protease inhibitor medications available, a cure may be possible. Encourage them to consult with their health care provider, or suggest involvement in a research study at the University of Utah (contact UDOH for contact information for study coordinators) for treatment options.

**APPENDIX C:**

# Hepatitis C Virus (HCV) Infection Testing for Diagnosis




*Samples with high s/co ratios usually (>95%) confirm positive, but supplemental serologic testing was not performed. Less than 5 of every 100 might represent false-positives; more specific testing should be requested, if indicated.

†Recombinant immunoblot assay

**APPENDIX D:**

# Reference for Interpretation of HCV Test Results

| If Your HCV Test Result Is: | | | Interpretation | | Action |
|---|---|---|---|---|---|
| | Anti-HCV Supplemental Test | | | | |
| Anti-HCV Screening Test* | RIBA† | or HCV RNA | Anti-HCV | HCV Infection | Additional Testing or Evaluation |
| Negative | Not Needed | Not Needed | Negative | None | No |
| Positive | Not Done | Not Done | Not Known | Not Known | Supplemental Anti-HCV (RIBA) or HCV RNA |
| Positive | Not Done | Negative | Not Known | Not Known◆ | Supplemental Anti-HCV (RIBA) |
| Positive (high s/co ratio§) | Not Done | Not Done | Positive | Past/current | Evaluate for chronic infection and liver disease |
| Positive | Negative | Not Needed | Negative | None | No |
| Positive | Positive | Not Done | Positive | Past/current | Evaluate for chronic infection and liver disease |
| Positive | Positive | Negative | Positive | Past/current◆ | Repeat HCV RNA |
| Positive | Positive/ Not Done | Positive | Positive | Current | Evaluate for chronic infection and liver disease |
| Positive | Indeterminate | Not Done | Indeterminate | Not Known | Test for HCV RNA or repeat Anti-HCV testing |
| Positive | Indeterminate | Positive | Indeterminate | Current | Evaluate for chronic infection and liver disease |
| Positive | Indeterminate | Negative | Negative | None | No |

* EIA- enzyme immunoassay or CIA- enhanced chemiluminescence immunoassay
† Recombinant immunoblot assay, a more specific anti-HCV assay
◆ Single negative HCV RNA result cannot determine infection status as persons might have intermittent viremia.
§ Samples with high s/co ratios usually (>95%) confirm positive, but supplemental serologic testing was not performed. Less than 5 of every 100 might represent false-positives; more specific testing should be requested, if indicated.